Summary of the
Environmental Laboratory Advisory Board Teleconference
September 5, 1996

The Environmental Laboratory Advisory Board (ELAB) met by teleconference from 2:30 to 4:30 on Thursday, September 5, 1996. The meeting was led by ELAB Chair, Ms. Ramona Trovato, Director of Environmental Protection Agency's (EPA) Office of Radiation and Indoor Air (ORIA). A list of action items is given in Attachment A. A list of participants is given in Attachment B. The meeting opened with a discussion of the July 21, 1996, minutes. The minutes were approved with one correction.

INTRODUCTION

This purpose of this meeting of ELAB was to address the questions posed by EPA's Office of Water (OW) at the July 21, 1996, ELAB meeting regarding EPA's proposal to externalize the water Performance Evaluation (PE) program. Teleconference participants discussed the following key items included in OW's document. A copy of the full text of the OW document is given in Attachment C.

- Program Costs — What will be the impact of externalization on "small" laboratories? What will be the impact on government (i.e.,state and municipal) laboratories?

- Time Line Considerations — How much time will be required to implement an accreditation program for vendors? What are the principal implementation milestones? What is the time requirement for each?

- Technical Considerations — What factors will affect study comparability, and what steps can reasonably be taken to maximize study comparability nationwide? Are there vendors who can do microbiology, radiation, and aquatic toxicology tests?

- Policy Considerations — What are the potential conflict-of-interest and confidentiality considerations, and what steps can reasonably be taken to protect against them?

PROGRAM COSTS

PE Cost Survey

Ms. Barbara Hill briefly related the results of a survey to be presented at an IAETL meeting in Toronto this month. A total of 50 laboratories were surveyed with responses received from 33 laboratories measuring from 5,000 to 1,000,000 analytes per year. According to the laboratories surveyed, $500 per study was a reasonable cost for PE samples. Currently these laboratories spend between $800 and $1,200 per year to participate in PE programs. It was noted that in addition to the cost of PE samples, labor costs associated with analyzing PE samples are also significant. Labor costs are estimated to be about 20% of the accreditation costs.

Typical PE "Load"
Small laboratories primarily analyze water samples, but these laboratories report fewer analytical parameters than large laboratories. (Usually 11 analytes per sample are reported.) On the average, the analytical laboratories surveyed participated in eight accreditation programs; a few labs had less than five accreditations. Both water pollution (WP) and water supply (WS) laboratories analyzed PE samples twice a year.

PE Cost Structure
The use of multiple vendors to provide PE samples was considered to be logical if PE providers had comparable quality systems in place to ensure consistent PE sample quality. (For example, Wisconsin allows laboratories to choose WP samples, the state's samples, or samples from a commercial vendor.) Because of the analyte dependence of PE sample costs. For example, volatile organic compounds (VOCs) were expected to cost more than pH samples. A suggestion was made that the cost per ampule be adjusted according to the analytical parameter. However, the cost incurred to a PE provider would be the same for preparing a single ampule containing either one or ten parameters. ELAB recommended that PE sample costs should be based on the ampule, rather than the parameter.

Because of the large volume of laboratories (>35,000) expected to participate in the accreditation program, costs associated with customizing kits to include parameter-specific ampules were believed to outweigh the savings in ampules.

PE costs to laboratories vary from state to state. Some states charge laboratories for PE samples, whereas laboratories are not charged by other states. For example, drinking water laboratories in Kentucky pay only for microbiological samples, but the 33 laboratories surveyed by IAETL were charged by the states. Municipal laboratories analyze for organics, pesticides, microbiologicals, lead, and metals. When a laboratory is charged for an entire category of PE samples, the analyses of PE samples is more economical for the large laboratory than for the small laboratory. The significance of labor costs associated with analyzing the PE samples relative to the costs of the PE samples themselves was reiterated.

The cost of PE samples was examined from the perspective of the number of people served by a drinking water utility. On the average, a single person uses 40 to 50 gallons of water a day for a total of 18,250 gallons per year. Accreditation costs for a utility that serves 3,000 people average approximately $1,000 per year, or approximately $0.30 per person. Even if the costs associated with accreditation were doubled to $0.60 per person, the cost becomes $0.00003 per person per gallon. On the basis of these calculations, ELAB agreed that a city's willingness to support a quality PE program was not an issue. Dr. Evelyn Torres will provide rate information from the Fairfax County Water Authority at the next teleconference.

In order to provide an accurate perspective of the costs associated with accreditation programs incurred by small laboratories (supporting less than 3,000 people), ELAB concurred that data from a number of states must be utilized. The IAETL survey data included data from 33 laboratories in 15 states.

Laboratory Demographics
ELAB considered utilizing either historical EPA data or the catalog of accreditation/certification programs compiled by IAETL to predict demand for PE samples by identifying laboratory participation in a particular accreditation program. The question of the number of labs located in one state and accredited under a program in a different state was raised. This issue is particularly important for labs accredited in California and New York because of the in-state PE programs..

TIME LINE CONSIDERATIONS

The time required for states to change regulations was expected to be the determining factor in establishing a time line for accreditation. Although programs for the preparation of PE samples are already in place, protocols that design and control PE samples must be developed.

TECHNICAL CONSIDERATIONS

Study Comparability
The most critical factor influencing study comparability was considered to be PE sample design. ELAB concurred that technical issues, rather than political issues, should govern protocols for design and control of PE samples. By utilizing proven vendors, with comparable quality systems in place, reciprocity issues (dependent upon the states' confidence in the NELAC PE program) would be more easily addressed. Standard protocols for the design and control of PE samples and PE provider oversight will need to be in place by September 1997. In order to reach this goal, ELAB considered utilizing the following bodies to develop the protocols:

- the EPA;
- the NELAC Proficiency Testing Committee;
- a Standards organization, such as American Society of Testing and Materials (ASTM), American National Standards Institute, Inc. (ANSI), or International Organization for Standardization (ISO);
- an ELAB-designated subcommittee; or
- National Institute of Standards and Technology (NIST).

ELAB discussed the importance of technical expertise in developing the protocols and recognized that an ELAB subcommittee and/or task group(s) could draw upon both the public and private sectors for standard development. ELAB unanimously agreed that an ELAB subcommittee (and/or task groups) be formed to develop the protocols in lieu of an organization such as ASTM, ANSI, or ISO because of the short turn-around time needed. Additionally, suggestions were made that an ASTM member either be a part of, or chair, the subcommittee. ELAB members suggested that expertise also be solicited from ISO and Association of Official Analytical Chemists (AOAC) and that the subcommittee be limited to 20 members. Ms. Wendy Coleman will discuss these recommendations with assessing bodies such as the the American Industrial Hygiene Association (AIHA), the American Association for Laboratory Accreditation (A2LA), and the NSF International.

Microbiological, Radiation, and Aquatic Toxicology Samples
Microbiological, radiation, and aquatic toxicology test samples within EPA's program would be expected to follow the same schedule for program externalization of the WS and WP samples. Currently, there are a number of states that do not participate in microbiological PE testing. However, states that do participate in these programs are tested either once or twice per year.

POLICY CONSIDERATIONS

Conflict of Interest
The issue of conflict of interest from private-sector providers of PE samples was raised because of the importance of maintaining credibility of the NELAC PE program. ELAB concurred that strong PE oversight by EPA was necessary to address conflict-of-interest issues.

Prospective marketing (by a PE provider) of "PE-assist samples" (samples having a known analyte concentration and designed analogously to the PE samples) was discussed. Although restricting the kinds of samples marketed by PE providers was mentioned, ELAB members were uncertain whether this policy would constitute restraint of trade. The possibility of restricting a PE provider from selling samples within a specified concentration of the PE sample was also discussed, but ELAB considered that this approach would not sufficiently address the issue. On the other hand, EPA does not want to discourage the analysis of matrix-based standards, such as standard reference materials (SRMs), or quality control (QC) check samples, as a part of each analytical batch. ELAB was asked to consider the conflict of interest associated with marketing a PE sample and a "PE-assist sample", and to discuss this issue at the next teleconference.

NEXT MEETING
Ms. Ramona Trovato concluded the teleconference by asking participants to prepare to discuss the action items in Attachment A.

Attachment A

ACTION ITEMS
Environmental Laboratory Advisory Board Teleconference
September 5, 1996

ACTION	Date Completed
ELAB Members prepare to discuss: . Conflict-of-interest considerations that impact PE providers and PE-provider oversight programs. . The development of an ELAB subcommittee and/or task group(s) to develop protocols for the design and control of PE samples.	
The cost data to be provided from the Fairfax County Water Authority by **Dr. Evelyn Torres** for discussion at the next teleconference	

Attachment B

LIST OF PARTICIPANTS
Environmental Laboratory Advisory Board Teleconference
September 5, 1996

Name	Affiliation	Phone Numbers
Ramona Trovato, Chair	EPA, Office of Radiation and Indoor Air (ORIA)	T: 202/233-9320 F: 202/233-9651
Jeanne Mourrain, Designated Federal Officer	EPA, NERL-Research Triangle Park	T: 919/541-1120 F: 919/541-4101
Lynn Bradley	Association for State and Territorial Public Health Laboratory Directors (ASTPHLD)	T: 202/822-5227 F: 202/887-5098
Tom Bruursema	NSF International	T: 313/769-5575 F: 313/769-0109
Wendy Coleman	EPA, Office of Water	T: 202/260-5680 F: 202/260-7023
Ted Coopwood	EPA, NELAP	T: 202/233-9358 F: 202/233-9651
Thomas Coyner	Analytical Products Group	T: 614/423-4200 F: 614/423-5588
Bob Graves	EPA, NERL / Cincinnati	T: 513/564-7325 F: 513/569-7115
John Henshaw	Monsanto Corporation, representing the Society for Quality Assurance (SQA)	T: 314/694-8830 F: 314/694-8808
Wilson Hershey	Lancaster Laboratories, representing ACIL	T: 717-656/2301 F: 717/656-0450
Barbara Hill	International Association of Environmental Testing Laboratories (IAETL)	T: 703/739-2188 F: 703/739-2556
Kathy Hillig	BASF Corporation, representing Chemical Manufacturers Association (CMA)	T: 313/246-6334 F: 313/246-5226
Cynthia Lee	ASL	T: 502/962-6400 F: 502/962-6411
Evelyn Torres	Fairfax County Water Authority (FCWA)	T: 703/430-1170 F: 703/404-5059
Allen Verstuyft	Chevron Research, representing the American Petroleum Institute (API)	T: 510/242-3403 F: 510/242-5320
Bill Gutknecht, Support Contractor	Research Triangle Institute	T: 919/541-6883 F: 919/541-8778
Emily Williams Support Contractor	Research Triangle Institute	T: 919/541-6217 F: 919/541-5929

OFFICE OF WATER
ADVICE AND COMMENTS SOLICITED FROM ELAB

PROGRAM COSTS

1 What will be the initial (start-up) and continuing costs of the program to vendors and what are the principal cost elements (by study, i.e., WS, WP, DMRQA)?
2 What costs will be incurred by vendors to establish and maintain accreditation?
3 What is a reasonable price range for each of the studies?
4 What will the impact of externalization be on "small" laboratories? What will the impact be on government (i.e., state and municipal) laboratories?

TIME LINE CONSIDERATIONS

1 How much time will be required to implement an accreditation program for vendors; what are the principal implementation milestones; and what is the time requirement for each?
2 Once accreditation is granted, how much time will be needed for an individual vendor to issue its first study (by study, i.e., WS, WP, DMRQA)?
3 How many studies per year can the average vendor conduct?

TECHNICAL CONSIDERATIONS

1 What factors will affect study comparability and what steps can reasonably be taken to maximize study comparability nationwide?
2 Will the industry be able to fund research and development of new studies/products? What role can/should EPA play in the process of developing new studies/study design?
3 Are there vendors who can do microbiology, radiation, and aquatic toxicology tests?
4 I the Agency goes to the private sector will there be any "orphan" compounds and, if so, how should the Agency handle that situation?

POLICY CONSIDERATIONS

1 Who should bear the costs of "bad" studies? Are special provisions needed to protect laboratories from the consequences of participating in a study that is lager found to be faulty? Will there be sufficient market-induced financial incentives created to address the problem (if so, what are those incentives)?
2 What are the potential conflict of interest/confidentiality considerations and what steps can reasonably be taken to protect against them?